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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/417,478	10/13/99	MCCAFFERTY	J 28111/32729B

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EXAMINER

PONNALURI, P

ART UNIT

PAPER NUMBER

1627

DATE MAILED:

11/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/417,478

Applicant(s)
McCafferty et al

Examiner
P. Ponnaluri

Group Art Unit
1627



☒ Responsive to communication(s) filed on Feb 25, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 44-53 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 44 and 45 is/are rejected.

☒ Claim(s) 46-53 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

☒ received in Application No. (Series Code/Serial Number) 07/971,857.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1627

DETAILED ACTION

1. The amendment and response filed on 2/25/00 has been fully considered and entered into the application.
2. Claims 44-53 are currently being examined in this application.
3. The terminal disclaimer filed on 9/7/00 has been fully considered and entered into the application.
4. The double patenting rejection of the claims over US Patent 5,969,108 has been withdrawn in view of the terminal disclaimer filed by applicants on 9/7/00.
5. Applicant's arguments with respect to claims 44-53 have been considered but are moot in view of the new ground(s) of rejection.
6. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Applicant is invited to notice that boxes 2, 6 and 12 were checked by the draftsman in PTO 948. Applicant is encouraged to amend the specification so that the description of renumbered figure corresponds to the renumbered figures.
7. The use of the trademarks STRATACLEAN (in page 173, line 14) and MILLIPORE (in page 183, line 4) have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Art Unit: 1627

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 44-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The present claims are drawn to recombinant host cells harboring a library of nucleic acids fragments comprising fragments encoding a genetically diverse population of **a member of a specific binding pair.**

The specification in page 27 defines that a specific binding pair is **"a pair of molecules which are naturally derived or synthetically produced"**. Thus any two molecules which would bind to each other would read on the specific binding pair. The specification disclosure is directed to a library of a single chain polypeptide comprising a binding domain of an antibody (specific

Art Unit: 1627

binding pair member), which clearly do not provide an adequate representation regarding the open ended claimed library of nucleic acids encoding specific binding pair made by the presently claimed invention.

The specification discloses recombinant host cells comprising library of nucleic acids encoding single chain antibody, which meets the written description. However, claims 44-45 are directed to encompass any binding pair, i.e., receptor-hormone, enzyme-substrate, IgG-protein A, biotin-avidin, ligand-receptor... and so forth. None of these meet the written description provision of 35 U.S.C 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

With the exception of library of single chain antibody disclosed by the specification, the skilled artisan cannot envision the method of making the libraries of other specific binding pairs which would be displayed on the surface of a filamentous phage. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen

Art Unit: 1627

Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

Art Unit: 1627

Therefore, only recombinant host cells harboring a library of nucleic acids encoding single chain antibody, but not the full breadth of the claim meet the written description provision of 35 U.S.C 112, first paragraph.

11. Claims 44-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for recombinant cells harboring library of specific binding pair member comprising single chain antibody, does not reasonably provide enablement for recombinant cells harboring any other specific binding pair members. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The specification defines that the specific binding pair is a pair of molecules which are naturally derived or synthetically produced. The specification also discloses examples of specific binding pair members such as antigen-antibody, enzyme-substrate, hormone-receptor, ligand-receptor or avidin-biotin. However, the specification disclosure is based on library of single chain antibody displayed on the surface of a filamentous phage. The specification does not recite a library of any other specific binding pairs. The specification disclosure is insufficient to enable one skilled in the art to practice the invention without undue amount of experimentation. The specification provides inadequate direction or guidance regarding how to produce recombinant host cells harboring a library of specific binding pair members other than the library of single chain antibody. The breadth of claims encompass metals, enzymes, hormones, or any binding pairs such

Art Unit: 1627

as ICAM-cell adhesion molecules or CD2-cell adhesion molecules. The specification discloses specific binding pair member having only single chain antibody. The *In re Wands* factors to be considered in determination of undue experimentation are: the quantity of experimentation necessary, the amount of direction or guidance provided, the presence or absence of working examples, the nature of the invention, the state of the prior art, the predictability of the art and the breadth of the claims. The specification fails to teach library of specific binding pair members other than the single chain antibody, comprising any specific binding pair members such as ICAMs-cell adhesion molecules or avidin-biotin. The specification examples are drawn to library of single chain antibody molecules displayed on filamentous phage. The specification does not have sufficient guidance on how the members of the library other than the single chain antibody can be displayed on the surface of a phage. The specification does not have guidance to how to prepare library of compounds other than the polypeptides such as antibodies to display on the surface of the filamentous phage. At the time the invention was made it was not known to make library of compounds other than peptides which are displayed on the surface of a filamentous phage. In view of the nature of the invention, the amount of guidance present in the specification, and the breath of the claims, it would take undue trials and errors to practice the claimed invention.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1627

13. Claims 44-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44 recites the limitation "said specific binding pair members" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 44 recites 'in functional form', clarification is requested what does applicant mean by displayed on the surface of bacteriophage in functional form. It is not clear what function, applicants are requested to clarify. Does applicant mean that the specific binding pair is displayed on the outer surface of the phage and anchored to the phage coat through gene III? Applicants are requested to clarify.

Claim 44 recites 'host cells harboring a library of nucleic acids', clarification is requested what does applicant mean by host cells harboring a library of nucleic acids. Does applicant mean that each host cell contains a library or each host cell contains a single nucleic acid fragment encoding a specific binding pair member?

Applicants are requested to amend 'a said fusion' in claim 44 as "said fusion".

14. Claims 46-53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. No claims are allowed.

Art Unit: 1627

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner can normally be reached on Monday to Thursday from 6.30 AM to 4.00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venakt, Ph.D., can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



P. Ponnaluri
Patent Examiner
Technology Center 1600
Art Unit 1627
14 November 2000